Department of Health and Human Services
Centers for Disease Control and Prevention

EXHIBIT 2

Sterilization or Disinfection of Medical Devices

The following principles are applicable to most questions CDC receives about sterilization or disinfection of patient-care equipment. However, these statements are not comprehensive.

General Principles

1. In general, reusable medical devices or patient-care equipment that enters normally sterile tissue or the vascular system or through which blood flows should be sterilized before each use. Sterilization means the use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores. The major sterilizing agents used in hospitals are a) moist heat by steam autoclaving, b) ethylene oxide gas, and c) dry heat. However, there are a variety of chemical germicides (sterilants) that have been used for purposes of reprocessing reusable heat-sensitive medical devices and appear to be effective when used appropriately, i.e., according to manufacturer's instructions. These chemicals are rarely used for sterilization, but appear to be effective for high-level disinfection of medical devices that come into contact with mucous membranes during use (e.g., flexible fiberoptic endoscopes).
2. Disinfection means the use of a chemical procedure that eliminates virtually all recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial endospores) on inanimate objects. There are three levels of disinfection: high, intermediate, and low. High-level disinfection kills all organisms, except high levels of bacterial spores, and is effected with a chemical germicide cleared for marketing as a sterilant by the Food and Drug Administration. Intermediate-level disinfection kills mycobacteria, most viruses, and bacteria with a chemical germicide registered as a "tuberculocide" by the Environmental Protection Agency (EPA). Low-level disinfection kills some viruses and bacteria with a chemical germicide registered as a hospital disinfectant by the EPA.
3. Heat stable reusable medical devices that enter the blood stream or enter normally sterile tissue should **always** be reprocessed using heat-based methods of sterilization (e.g., steam autoclave or dry heat oven).
4. Laparoscopic or arthroscopic telescopes (optic portions of the endoscopic set) should be subjected to a sterilization procedure before each use; if this is not feasible, they should receive high-level disinfection. Heat stable accessories to the endoscopic set (e.g., trocars, operative instruments) should be sterilized by heat-based methods (e.g., steam autoclave or dry heat oven).
5. Reusable devices or items that touch mucous membranes should, at a minimum, receive high-level disinfection between patients. These devices include reusable flexible endoscopes, endotracheal tubes, anesthesia breathing circuits, and respiratory therapy equipment.
6. Medical devices that require sterilization or disinfection must be thoroughly cleaned to reduce organic material or bioburden before being exposed to the germicide, and the germicide and the device manufacturer's instructions should be closely followed.
7. Except on rare and special instances (as mentioned below), items that do not ordinarily touch the patient or touch only intact skin are not involved in disease transmission, and generally do not necessitate disinfection between uses on different patients. These items include crutches, bedboards, blood pressure cuffs, and a variety of other medical accessories. Consequently, depending on the particular piece of equipment or item, washing with a detergent or using a low-level disinfectant may be sufficient when decontamination is needed. If noncritical items are grossly soiled with blood or other body fluids, follow instructions outlined in the section on **HIV-related sterilization and disinfection** of this information system.

Exceptional circumstances that require noncritical items to be either dedicated to one patient or patient cohort, or subjected to low-level disinfection between patient uses are those involving:

1. Patients infected or colonized with vancomycin-resistant enterococci or other drug-resistant microorganisms judged by the infection control program, based on current state, regional, or national recommendations, to be of special or clinical or epidemiologic significance
   or
2. Patients infected with highly virulent microorganisms, e.g., viruses causing hemorrhagic fever (such as Ebola or Lassa).

If you have questions about a low- or intermediate-level disinfectant and certain sterilants, contact the manufacturer, or the Antimicrobial Program Branch, Environmental Protection Agency (EPA) hotline (703) 308-0127 or email: **info_antimicrobial@epa.gov**. The EPA is the federal regulatory agency for low- or intermediate-level disinfectants and some sterilants.

If you have questions about high-level disinfectants (sterilants), or how to clean, disinfect or sterilize a particular medical device, first contact the manufacturer of the product. If you are unable to obtain sufficient information in this manner, contact the Food and Drug Administration (FDA) regional office or the FDA Center for Devices and Radiological Health at (301) 443-4690. FDA is the federal regulatory agency for safe and effective use of medical devices and is now also responsible for regulation of chemical sterilants.

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